DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

[Docket No. 98E-0478]

Determination of Regulatory Review Period for Purposes of Patent Extension; Requip

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Requip and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESS: Written comments and petitions should be directed to the Dockets Management Branch, between 9 a.m. and 4 p.m., Monday through Friday, Dockets Management Branch, c/o Office of the Secretary, HHS, Room 1A-33, 5630 Fishers Lane, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-672) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products (both testing phase begins when the application for approval the clinical investigations of the drug becomes

(h) Paying carriers for provided transportation services through use of a Government charge card.


Allan J. Zaic,
Assistant Commissioner, Office of Transportation and Property Management.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

[Docket No. 98E-0788]

Determination of Regulatory Review Period for Purposes of Patent Extension; Sucralose

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that the applicable regulatory review period for Sucralose was 3,356 days. Of this time, 2,729 days occurred during the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Requip (ropinirole). Requip is indicated for the treatment of the signs and symptoms of idiopathic Parkinson's disease.

FDA has determined that the applicable regulatory review period for Sucralose was 3,356 days. Of this time, 2,729 days occurred during the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

3. The date the application was approved: September 19, 1997. FDA has verified the applicant's claim that NDA 20-658 was approved on September 19, 1997.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,826 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before February 19, 1999, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before June 21, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.


Thomas J. McGinnis,
Deputy Associate Commissioner for Health Affairs.
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BILLING CODE 4160-01-F
the regulatory review period for Sucralose and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that food additive.

**ADDRESSES:** Written comments and petitions should be directed to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Brian J. Malkin, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–6620.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product’s regulatory review period forms the basis for determining the amount of extension an applicant may receive. A regulatory review period consists of two periods of time: a testing phase and an approval phase. For food additives, the testing phase begins when a major health or environmental effects test involving the food additive begins and runs until the approval phase begins. The approval phase starts with the initial submission of a petition requesting the issuance of a regulation for use of the additive (“petition”) was initially submitted with respect to the food additive. FDA has determined that the applicable regulatory review period for Sucralose is 5,332 days. Of this time, 1,260 days occurred during the testing phase of the regulatory review period, while 4,072 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date a major health or environmental effects test (“test”) involving this food additive additive product was begun: August 30, 1983.
2. The date the petition requesting the issuance of a regulation for use of the additive (“petition”) was initially submitted with respect to the food additive. FDA has verified the applicant’s claim that the test was begun on August 30, 1983.
3. The date the petition became effective: April 3, 1998. FDA has verified the applicant’s claim that the regulation for the additive became effective on April 3, 1998.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 730 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before February 19, 1999, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before June 21, 1999, for a redetermination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.


Thomas J. McGinnis,
Deputy Associate Commissioner for Health Affairs.

**BILLING CODE 4160–01–F**

**DEPARTMENT OF THE INTERIOR**

**Fish and Wildlife Service**

**Endangered and Threatened Species Permit Applications**

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of receipt of applications.

The following applicants have applied for permits to conduct certain activities with endangered species. This notice is provided pursuant to section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 et seq.).

**Permit Numbers TE006010 and TE006012**

Applicant: Dr. Steven J. Taylor, Center for Biodiversity, Illinois Natural History Survey, Champaign, Illinois.

The applicant requests two permits to take (collect) endangered Illinois Cave Amphipod (Gammarus acheron) in Monroe and St. Clair Counties, Illinois. Research is proposed for scientific purposes to determine environmental threats to extant amphipod populations and to determine components of distribution of the species. Activities are proposed for the purpose of survival and enhancement of the species in the wild.

**Permit Number TE006007**

Applicant: Dr. Julian Lewis, Clarksville, Indiana.

The applicant requests a permit to take (collect) endangered Illinois Cave Amphipod (Gammarus acheron) in Monroe and St. Clair Counties, Illinois.